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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YEH, JENNER	

ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,048	KORNERUP ET AL.	
	Examiner	Art Unit	
	JENNER YEH	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to the amendment filed on November 3, 2009. As directed by the amendment, claims 1-16 and 18-27 are presently pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-6, 11, 12, 14, 19, 20, 22-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mejslov (US 6123690) in view of Douglas et al (US 6749589).

4. RE claims 1, 23, 26 and 27, Mejslov discloses an infusion set (abstract) comprising an infusion part 19 for insertion into a patient and a connector 21 for connecting the infusion part with a medical device, "pump", through a tube 22 (Figure 10; Col 4, lines 14-19), the connector 21 being axially displaceable relative to the infusion part 19 (Figure 11),

the infusion part comprising:

a base 19 connected to an adhesive support (Figure 15; Col 2, lines 53-54), the base part including a first set of guides 36, "grooves", (Figure 16; Col 4, lines 55-57) and two retention devices 25 for releasably locking the connector 21 to the infusion part (Figure 10; Col 4, lines

20-25), the retention devices 25 extending upwardly from an upper surface of the base (Figure 11);

a first cannula 20 extending from the base 19 and being in fluid communication with a cavity 33, the cavity 33 being adapted to receive a second cannula 30 extending from the connector 21 (See Figure 14 for cannula 30 connected to connector 21), where the second cannula 30 is in fluid communication with the tube 22 (Figure 15); and

the connector 21 comprising a second set of guides adapted to fit with the first set of guides (Col 2, lines 47-52; ie. connector fins have corresponding grooves to fit with grooves on the infusion housing) and two arms 23 adapted to fit with the retention devices 25 (Figure 12), the arms movable in a laterally inwardly and laterally outward away from the base to allow disengagement of the arms from the retention devices (Col 2, lines 38-42 and Col 4, lines 20-25; ie. locking arms 23 are flexed laterally inward along the portion that is pressed in, flexed laterally outward along barb 24 at the arms distal end).

Mejslov's devices arms 23 are capable of being flexed upward (ie. arms 23 are flexible, Col 2, lines 38-42) where upward flexing would disengage connector 21 from infusion part 19 except that the arms' upward movement is slightly hampered by groove 36 (Figures 10, 12 and 16). Douglas et al teach an infusion set where a connector 206 is connected to an infusion part 202 via flexible arms 260 engaging with retention devices 280 (See Figures 4, 5 and 12) and the connector 206 is guided into the infusion part via guide pins 216/218 on connector 206 (Figure 12) inserted into guide pin holes 246/244 on infusion part 202 (Figures 3-5 and 7).

It would have been an obvious matter of engineering design choice to substitute Mejslov's guide means with guide pins in guide holes, as taught by Douglas, to achieve the

desired purpose of axially guiding the connector into the infusion part. Elimination of the side grooves on Mejslov's device would allow arms 23 to flex upward.

5. RE claim 3, Mejslov discloses arms 23 are flexible (Col 2, lines 38-42) and thus capable of moving in a direction perpendicular to the base.

6. RE claim 4, Mejslov in view of Douglas et al disclose the arms flexibly connected to the second set of guides via a groove (ie. in modifying Mejslov's device and incorporating guide pins on connector 21, a groove would be formed between the guide pin and arms 23 since arms 23 entirely encompass the insertion end of the connector, see Figures 12 and 14). As discussed above, Mejslov discloses arms 23 are flexible (Col 2, lines 38-42).

7. RE claims 5 and 6, Mejslov discloses retention devices 25 are flexibly connected to base 19 and base 19 comprises two flaps on which the retention devices are positioned (Figures 10 and 11; ie. retention devices 25 are disposed on two laterally projecting flaps from either side of the base's cannula end top section; since all materials have some inherent flexibility and the retention devices are connected to the base via the overhanging projecting flaps, the retention devices are flexibly connected to the base).

8. RE claims 11 and 12, Mejslov discloses the retention devices comprise a step 25 (Figure 12) and comprise a triangular shape (Figure 12; ie. retention devices 25 include the corner between the retention step and the base top part, the corner having a triangular shape).

9. RE claim 14, Mejslov discloses the medical device is a pump (Col 4, lines 15-19) but does not disclose the device is an insulin pump. Insulin pumps are well known in the art and Douglas et al teach an insulin pump as a drug delivery means to infuse a drug (Col 1, lines 48-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify Mejslov's device and connect it to an insulin pump, as taught by Douglas, for the purpose of delivering insulin.

10. RE claim 19, Mejslov disclose a platform 27 on base 19 for stabilizing the connector (Figures 11 and 13; Col 4, lines 33-36) but do not disclose second cannula 30, "needle", extends from a recessed front portion in a central part of connector 21 and the first set of guides comprising two stabilizing fins. Douglas et al disclose the second cannula, "needle", extends from a central part of the connector and is recessed relative to a front portion of the central part (Figure 12; ie. needle 220 is recessed within guiding pins 216/218 and recessed in distal portion 296) and disclose base housing 202 has two stabilizing fins 242 to guide the connector 206 (Figure 5; Col 7, lines 15-24). It would have been an obvious matter of engineering design choice to modify Mejslov's device to include a recessed needle and two stabilizing guiding fins, as taught by Douglas, since the modifications are mere substitutions of known components.

11. RE claim 20, Mejslov discloses an injector device for subcutaneous introduction of the first cannula of the infusion part into the skin of a patient (Figure 18; Col 4, lines 61-67).

12. RE claims 22 and 25, Mejslov discloses a membrane 32, "septum", covering the cavity (Figure 15; Col 4, lines 41-45).

13. Claims 2, 7, 8, 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mejslov (US 6123690) and Douglas et al (US 6749589) and further in view of Marggi et al (US 2001/0053889).

14. RE claim 2, Mejslov in view of Douglas et al disclose all the claimed elements, as discussed above, and Mejslov discloses the connector 21 is symmetrical about an axis perpendicular to a main plane (Figure 14) but does not disclose the connector 21 symmetrical about the main plane. Marggi et al teach an infusion set where a connector 3, "needle holder", exhibits symmetry about the main plane of the infusion set (Figures 2 and 4) and teach this symmetry simplifies handling since the connector can be connected even when it is flipped upside down (paragraph 0034).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mejslov's connector such that it were symmetrical about a main plane of the device, as taught by Marggi, for the purpose of making the device easier to use.

15. RE claims 7-8 and 24, Mejslov in view of Douglas et al disclose all the claimed elements, as discussed above, but does not disclose the adhesive is a plaster connected to a lower surface of the base where the first cannula passes through the adhesive. Mejslov discloses the device is connected to a patient by means of adhesive material (Col 2, lines 53-54). Marggi teaches a means of affixing an infusion set to a patient where a plaster adhesive is affixed onto the bottom of an infusion housing and the cannula to be inserted passes from the housing through the adhesive (Figure 1; paragraph 0029).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mejslov's device to include a plaster adhesive attached to the bottom of the infusion part, as taught by Marggi, for the purpose of attaching the infusion device to a patient.

16. RE claim 13, Mejslov in view of Douglas et al disclose all the claimed elements, as discussed above, but does not disclose the tube is fastened to the connector by glue. Glue is well known in the art as a means of connecting two components, as exemplified by Marggi (paragraph 0027), and it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect Mejslov's tube to the connector with glue for the purpose of putting together two components.

17. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mejslov (US 6123690) and Douglas et al (US 6749589) and further in view of Wojcik (US 6572586).

18. RE claims 9 and 18, Mejslov in view of Douglas et al discloses all the claimed elements, as discussed above, but does not disclose the connector and infusion part comprising two different plastics material and does not disclose the infusion part or connector comprises polypropylene. Choosing a suitable material that is well known in the art requires only routine skill in the art, and Wojcik '586 teaches suitable plastic materials such as polypropylene, polycarbonate or polyurethane that can be used to manufacture infusion set bases (Col 4, lines 49-51) or infusion set connectors (Col 5, lines 49-51).

It would have been obvious to one of ordinary skill in the art to manufacture Mejslov's infusion part and connector such that both parts comprise different plastics as an obvious matter of design choice; one of ordinary skill in the art could manufacture the two parts separately using whichever materials were most economical to the design. It would further have been obvious to

manufacture Mejslov's device with polypropylene, as taught by Wojcik, for the purpose of selecting an appropriate biocompatible material.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mejslov (US 6123690) and Douglas et al (US 6749589) and further in view of Reiterman (US 3670727).

20. RE claim 10, Mejslov in view of Douglas et al discloses all the claimed elements, as discussed above, but does not disclose the infusion part and the connector being of two different visual tones. Reiterman teaches an infusion set where a base of the infusion set, "wings", is of a different color than the rest of the infusion set (Col 2, lines 42-48; Figures 1 and 2). Reiterman teaches that using different colors helps identify and differentiate between different bases (Co 2, lines 42-48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mejslov's infusion set such that the connector and infusion part were of different colors, a taught by Reiterman, as an obvious matter of design choice and to easily identify infusion sets with different cannulas.

21. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mejslov (US 6123690) and Douglas et al (US 6749589) and further in view of Brantigan (US 3893448).

22. RE claims 15 and 16, Mejslov in view of Douglas et al discloses all the claimed elements, as discussed above, and disclose cannula 20 is a soft cannula (Col 4, lines 14-16), but does not disclose the cannula made from a thermoplastic elastomer such as silicone rubber. Brantigan teaches a cannula for insertion into a patient where the cannula is made of silicone rubber (Col 2, lines 58-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mejslov's cannula such that it is manufactured from silicone rubber, as taught by Brantigan, for the purpose of providing a soft cannula that can be safely inserted into patients.

23. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mejslov (US 6123690) and Douglas et al (US 6749589) and further in view of Wojcik (US 2002/0077599) and Gaba (US 5697907).

24. RE claim 21, Mejslov discloses the injector device has a housing, a back 37, longitudinally extending guides 39 and a needle 38 for insertion (Figure 18). Mejslov does not disclose the injector device has a slidable member longitudinally slidable within the housing, a spring between the housing back and slidable member, locking members for retaining the spring in a compressed state, release members for disengaging the locking members and a pivoting member pivotable from a position allowing for insertion of the needle to a position embracing the needle.

Wojcik '599 teaches an injector device for inserting an infusion set where the injector device, "inserter assembly", includes a slidable member 30, "retainer", a spring 92 between the slidable member and a back of the injector device, locking members 106 for maintaining the spring in a compressed state and release members 102/98, "release button/release lever", for disengaging the locking members (Figures 4 and 5; paragraph 0034). Wojcik '599 teaches this automatic inserter helps patients ensure correct placement of the cannula (paragraphs 0007-0008).

Gaba teaches an insertion needle device with where the insertion needle 135 is contained within a housing 342 that has a pivotable member 348, "retainer", that is pivotable between one position where the needle can be extended and inserted into a patient (Figure 13) and a second position where the pivotable member 348 embraces the needle (Figure 14). Gaba teaches that the pivotable member functions as a safety device to prevent the needle from extending out after insertion (Col 5, line 61 to Col 6, line 7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Mejslov's insertion device to include an automatic insertion mechanism including a spring, lock and release mechanism, as taught by Wojcik, and a pivotable member, as taught by Gaba, for the purpose of ensuring correct placement of the cannula and providing enhanced safety precautions.

Response to Arguments

25. Applicant's arguments with respect to claims 1 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNER YEH whose telephone number is (571)270-7836. The examiner can normally be reached on Monday-Thursday, 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. Y./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763